SEP 1 7 2008

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Section II. 510(k) SUMMARY

A. Device Name

Proprietary Name

TERUMO® Surshield® SAFETY I.V. CATHETER or similar proprietary name

Classification Name

Intravascular Catheter (880.5200)
Panel & Product Code: FOZ
Classification: Class II

Common Name

Intravascular catheter with needle protection device

B. Predicate Device

The TERUMO® Surshield® SAFETY I.V. CATHETER manufactured by Terumo Corporation is substantially equivalent to with respect to intended use, design, technology/principles of operation, materials and performance:

1. K891087 TERUMO® SURFLO® I.V. Catheter for the catheter portion only
2. K991406 TERUMO® SURFLASH® I.V. Catheter for the needle portion only
3. K020785 B.BRAUN Introcan Safety™ I.V. Catheter

The differences between the devices do not raise any new issues of safety or effectiveness.

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C. Intended Use

The TERUMO® Surshield® SAFETY I.V. CATHETER is inserted into the patient's vascular system for short term (<30 days) use to withdraw blood samples, administer fluids intravenously, or through which to place monitoring equipment such as blood pressure monitors. The needle shield feature aids in the prevention of needle stick injuries. These catheters may be used for any patient population with consideration given to adequacy of vascular anatomy and appropriateness for the solution being infused and duration of therapy.

D. Description

The TERUMO® Surshield® Safety I.V. Catheter are devices consisting of an over-the needle, peripheral catheter made of an a slender, flexible, radio-opaque, plastic catheter with a hub that is inserted into the patient's vascular system for short term (<30 days) use to withdraw blood samples, administer fluids intravenously, or through which to place monitoring equipment such as blood pressure monitors. The stainless steel cannula is placed in the catheter to maintain rigidity and is withdrawn after the catheter is placed in the vascular system. The sharp end of the inner needle is covered by the steel guard as the needle is withdrawn from catheter's hub to aid in the prevention of needle stick injuries. This is a passive safety mechanism.

E. Principle of Operation / Technology

The TERUMO® Surshield® SAFETY IV CATHETER is operated manually.

F. Design / Materials

The materials are the same materials as used in the TERUMO® SURFLO® I.V. Catheter (K891087) and the TERUMO® SURFLASH® I.V. Catheter (K991406).

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G. Specifications

Product code	Catheter gauge	Color code	Catheter length	Catheter O.D	Catheter I.D	Cannula gauge	Flow rate	Lumen volume*
SR*SFA1832A	18G	Deep Green	1-1/4"(32mm)	1.3mm	0.95mm	20G	100mL/min	23 μL
SR*SFA2032A	20G	Pink	1-1/4"(32mm)	1.1mm	0.80mm	22G	60mL/min	16 μL
SR*SFA2225A	22G	Deep Blue	1"(25mm)	0.9mm	0.60mm	24G	35mL/min	7 μL
SR*SFA2419A	24G	Yellow	3/4"(19mm)	0.7mm	0.47mm	27G	15mL/min	3 μL

*Catheter only

H. Performance

The following tests were performed on the TERUMO® Surshield® SAFETY IV CATHETER manufactured by Terumo Corporation:

1. Reactive force to close shutter (Reaction force generated by the safety mechanism)
2. Force to detach safety cover from catheter hub (Force to activate safety feature)
3. Initial sliding friction (Catheter and Needle attachment)
4. Tensile strength of safety cover and needle (Break strength of safety mechanism)
5. Force to needle breaking safety cover (Puncture resistance of the needle shield)
6. Flow rate

I. Additional Safety Information

The sterility of the device is assured using a sterilization method validated in accordance with ISO 11135-2007. The Surshield® Safety IV Catheter is sterilized to provide a Sterility Assurance Level (SAL) of 10^{-6}.

Ethylene oxide residual levels (EtO and ECH) resulting from EtO sterilization will not exceed the maximum residue limits in accordance with ISO 10993-7: Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals and AAMI TIR19 Guidance for ANSI / AAMI / ISO 10993-7:1995, Biological Evaluation for Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals (and amendment).

The addition of the safety devices requires no additional biocompatibility testing, because there is no blood/fluid contact.

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J. Substantial Equivalence

The TERUMO® Surshield® SAFETY I.V. CATHETER manufactured by Terumo Corporation is substantially equivalent to with respect to intended use, design, technology/principles of operation, materials and performance:

1. K891087 TERUMO® SURFLO® I.V. Catheter for the catheter portion only
2. K991406 TERUMO® SURFLASH® I.V. Catheter for the needle portion only
3. K020785 B.BRAUN Introcan Safety™ I.V. Catheter

The differences between the devices do not raise any new issues of safety or effectiveness.

K. Submitter Information

Date Prepared: 08/06/2008

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 7 2008

Terumo Medical Corporation
C/O Mr. Mark Job
Responsible Third Party Officer
Regulatory Technology Services LLC
1394 25th Street NW
Buffalo, Minnesota 55313

Re: K082362
Trade/Device Name: TERUMO® Surshield® SAFETY I.V. CATHETER
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: II
Product Code: FOZ
Dated: September 3, 2008
Received: September 4, 2008

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K032362

Device Name: TERUMO® Surshield® SAFETY I.V. CATHETER

Indications For Use:

The TERUMO® Surshield® SAFETY I.V. CATHETER is inserted into the patient's vascular system for short term use (<30 days) to withdraw blood samples, administer fluids intravenously, or through which to place monitoring equipment such as blood pressure monitors. The needle shield feature aids in the prevention of needle stick injuries. These catheters may be used for any patient population with consideration given to adequacy of vascular anatomy and appropriateness for the solution being infused and duration of therapy.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K032362